



## KNOWLEDGE SHARING AND CAPACITY BUILDING

- Updates about *case-sharing collaborative assessment pilot programs* such as the ICMRA, ACCESS, ASEAN Joint Review, Orbis, etc.
- Discussed *considerations and expectations for real implementation of collaborative assessment* in the future for both health authorities and the industry.
- The *scope of M4Q (R2) will be broader* than that of R1, and it will cover all modalities.
- M4Q (R2) is *expected to create a globally harmonized dossier* which will improve patients' access.

## CMC STRATEGY FORUM JAPAN 2024 BY THE NUMBERS



**First-Time Attendees**

**46**



**Regulators Participation**

**17**



**Company Participation**

**38**



**Country Participation**

**9**

China | Denmark | Japan | Malaysia | Senegal | Singapore | South Korea | Switzerland | United States

